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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/519,224	03/06/2000	John C. Yundt-Pacheco	HEMA.69528	7948

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EXAMINER

SUN, XIUQIN

ART UNIT PAPER NUMBER

2863

DATE MAILED: 06/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/519,224

Applicant(s)

YUNDT-PACHECO, JOHN C.

Examiner

Xiuqin Sun

Art Unit

2863

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 17,37 and 44 is/are objected to.
- 8) ☒ Claim(s) 1-16,18-36,38-43 and 45-55 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-16, 18-20, 41-43 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer et al. (U.S. Pat. No. 5646046) in view of Lin (U.S. Pat. No. 5532941).

Fischer et al. teach a method for modifying data from a group of laboratory instruments (col. 26, lines 56-67; col. 27, lines 1-11) which comprises the steps of: obtaining data indicative of testing specimen outputs of a laboratory instrument (col. 6, lines 7-9; col. 7, lines 3-32; col. 26, lines 57-67 and col. 27, lines 1-11); and normalizing the data according to a reference (col. 7, lines 3-32; col. 19, lines 59-67; col. 20, lines 61-67; col. 21, lines 1-67; col. 22, lines 1-42; col. 26, lines 57-67 and col. 27, lines 1-12). The teachings of Fischer et al. further include: receiving the laboratory instrument outputs via a network/Internet communication link (col. 20, lines 25-26); receiving the laboratory instrument outputs via a manual input (col. 13, lines 64-67). The normalization step taught by Fischer et al. includes: obtaining control specimen data and generating a normalization curve according to the control specimen data (col. 20, lines 61-67;

col. 21, lines 1-67; and col. 22, lines 1-42). The Fischer method further teaches that the normalization curve can be generated by applying a linear regression, and/or a nonlinear regression, and/or a spline to a group of control specimen data and measuring the curve error for each curve (col. 21, lines 33-47; lines 57-58; and col. 22, lines 14-42); and adjusting the laboratory instrument data according to the obtained normalization curve (col. 21, lines 32-43). The Fischer method further teaches returning the optimum curve with the minimized curve error as the normalization curve (col. 8, line 2-14; col. 22, lines 39-42). The normalization step taught by Fischer et al. further includes: mapping the testing specimen group output according to the normalization curve (col. 21, lines 35-43; col. 27, lines 8-11); the normalization curve is generated for a single laboratory instrument (col. 5, 57-64; col. 21, lines 32-43; col. 26, lines 66-67), and can further be applied to each instrument in a group of laboratory instruments (col. 26, lines 60-67). The Fischer method further teaches: outputting the normalized data (col. 3, lines 58-59; and col. 21, lines 36-41); and a computer-readable medium having computer-executable instructions for performing the steps recited in claim 1 (col. 7, lines 59-62; col. 8, lines 14-28).

Fischer et al. do not mention explicitly: obtaining data indicative of testing specimen outputs of a group of laboratory instruments; normalizing the data according to a control group, wherein the control group comprises data indicative of a comparison group of laboratory instruments; the outputting step includes displaying the normalized data on a network; a computer system having a memory, an operating system and a central processor;

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Lin teaches the steps and means of obtaining data indicative of outputs of a group of lab instruments; and normalizing the data according to a control group, wherein the control group comprises data indicative of a comparison group of laboratory instruments (Figs. 5 and 8A-8C; abstract; col. 2, lines 43-48, lines 53-56; col. 3, lines 6-11, lines 40-49, lines 60-63; col. 6, lines 5-28; col. 7, lines 57-67; col. 8, lines 1-67; col. 9, lines 1-34; col. 10, lines 21-67; col. 11, lines 1-12; col. 21, lines 66-67 and col. 22, lines 1-15); the outputting step includes displaying the normalized data on a network, and sending the normalized data to the group of laboratory instruments (Fig. 5; col. 5, lines 26-29; col. 23, lines 16-27; and col. 25, lines 13-20). Lin further teaches the step and means of normalizing the one group testing specimen output with another group testing specimen output (col. 2, lines 49-58 and col. 25, lines 9-13). The teachings of Lin further include a computer system having a memory, an operating system and a central processor (Figs. 1 and 5; col. 6, lines 66-67 and col. 7, lines 1-51).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to include the Lin group data collection, normalization technique and the computer system in the Fischer method in order to reduce the instrument-to-instrument variability in data obtained from a group of lab instruments to allow comparative data analysis electronically without confusion or loss of confidence (Lin, abstract).

3. Claims 21-36, 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer et al. in view of Lin.

The Fischer and Lin combination teaches a method and system that include the subject matter discussed above except that: modifying data from more than one group of laboratory instruments.

In view of the teaching of Fischer et al. (col. 26, lines 56-67; col. 27, lines 1-11; col. 20, lines 20-26; col. 20, lines 61-67; col. 21, lines 1-67; and col. 22, lines 1-42) and Lin (Figs. 5 and 8A-8C; abstract; col. 2, lines 43-48, lines 53-56; col. 3, lines 6-11, lines 40-49, lines 60-63; col. 6, lines 5-28; col. 7, lines 57-67; col. 8, lines 1-67; col. 9, lines 1-34; col. 10, lines 21-67; col. 11, lines 1-12; col. 21, lines 66-67 and col. 22, lines 1-15), one having ordinary skill in the art would be able to apply the same technique to carry out the method for modifying instrument results to other groups of laboratory instruments. The mere application of a known method to more than one group of laboratory instruments by those skilled in the art would have been obvious.

4. Claims 45-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer et al. in view of Lin.

The Fischer and Lin combination teaches a method and system that include the subject matter discussed above except that: standardizing instrument results from a plurality of laboratory instruments.

It would have been obvious that the procedure for standardizing instrument results recited in claims 45-54 is a modification from the normalization procedure recited in claim 1, by adding the step of adjusting the instrument data according to the normalization curve. In view of the teachings disclosed by Fischer et al. and Lin, one having ordinary skill in the art would be able to apply

the same technique to carry out the method for standardizing the outputs from a group of laboratory instruments.

Allowable Subject Matter

5. Claims 17, 37 and 44 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Reasons for Allowance

6. The following is an examiner's statement of reasons for allowance:

The primary reason for the allowance of claims 17 and 37 is the inclusion of the method step of displaying the normalized data on a network. It is this limitation found in each of the claims, as it is claimed in the combination, that has not been found, taught or suggested by the prior art of record which makes these claims allowable over the prior art.

The primary reason for the allowance of claim 44 is the inclusion of the limitation that one or more groups of laboratory instruments include a laboratory information system coupled to individual laboratory instruments and in communication with the normalization server. It is this limitation found in each of the claims, as it is claimed in the combination, that has not been found, taught or suggested by the prior art of record which makes these claims allowable over the prior art.

Response to Arguments

7. Applicant's arguments with respect to claims 1-14, 16, 19-33, 35-36, 39-43 and 45- 55 have been considered but are moot in view of the new ground(s) of rejection.

Claims 1-16, 18-36, 38-43 and 45-55 are rejected as new art (U.S. Pat. No. 5532941) has been found to teach the steps of obtaining data from a group of instruments and then normalizing the data according to a control group. For detailed response, please refer to the section 2-4 set forth above in this Office Action.

Contact Information

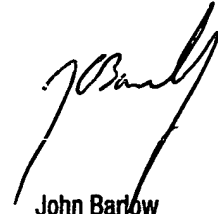
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Xiuqin Sun whose telephone number is (703)305-3467. The examiner can normally be reached on 7:00am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Barlow can be reached on (703)308-3126. The fax phone numbers for the organization where this application or proceeding is assigned are (703)872-9318 for regular communications and (703)872-9319 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0956.

XS
XS

June 15, 2003



John Barlow
Supervisory Patent Examiner
Technology Center 2800